LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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August 31, 2000

OVERNIGHT COURIER 8/31/00

Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

This petition is submitted in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Glucophage® (Metformin HCl) Tablets, 625 mg and 750 mg, (NDA No. N20357), by Bristol-Myers Squibb Co., have been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products which are eligible for submission as abbreviated new drug applications in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("The Orange Book"). The current (20th) edition of the Orange Book includes Glucophage® Tablets, 625 mg and 750 mg in the Discontinued Drug Product List section (applicable page attached). A listing in this section of the Orange Book indicates that those drug products designated by the symbol "*" have already been provided with a determination as to whether the drug products were not marketed or withdrawn for safety or efficacy reasons. The listing for Glucophage® (Metformin HCl) Tablets, 625 mg and 750 mg are not designated by the symbol "*". Therefore, it appears that a determination has not been made as to whether the listed drug has been voluntarily withdrawn for safety or effectiveness reasons.

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug application for the reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a

DOP.1496

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determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161{a}{1}).

As stated, Bristol-Myers Squibb's Glucophage® (Metformin HCl) Tablets, 625 mg and 750 mg, are not available for sale in the marketplace. Because there is no current commercial distribution of this drug product and because this drug product is listed in the Discontinued Drug Product List section, it is requested that the FDA determine whether Bristol-Myers Squibb's decision not to market Glucophage® (Metformin HCl) Tablets, 625 mg and 750 mg was for reasons of safety or effectiveness.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided if so requested.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Gordon R. Johnston
Associate

Attachment: Discontinued Drug Product List Section Regarding: Glucophage® Tablets, 625 mg and 750 mg

cc: Nasser Mahmud (OGD)
Leon Lachman, Ph.D. (LCS)

36k0244a

METAPROTERENOL SULFATE

SOLUTION; INHALATION
METAPROTERENOL SULFATE

DEY	0.33%	N71806 001
		AUG 05, 1988
	0.5%	N71805 001
		AUG 05, 1988
	5%	N70805 001
		AUG 17, 1987
MORTON GROVE	5%	N72190 001
		JUN 07, 1988

SYRUP; ORAL
METAPROTERENOL SULFATE

MORTON GROVE	10MG/5ML	N71656 001
		OCT 13, 1987

TABLET; ORAL
METAPROTERENOL SULFATE

AM THERAP	10MG	N72054 001
		JUN 23, 1988
	20MG	N72055 001
		JUN 23, 1988
ROSEMONT	10MG	N71013 001
		JAN 25, 1988
	20MG	N71014 001
		JAN 25, 1988

METARAMINOL BITARTRATE

INJECTABLE; INJECTION
METARAMINOL BITARTRATE

AM PHARM PARTNERS	EQ 10MG BASE/ML	N80431 001
ELKINS SINN	EQ 10MG BASE/ML	N83363 001
SEARLE	EQ 10MG BASE/ML	N86418 001
	EQ 20MG BASE/ML	N86418 002

METFORMIN HYDROCHLORIDE

TABLET; ORAL
GLUCOPHAGE

BRISTOL MYERS SQUIBB	625MG	N20357 003
		NOV 05, 1998
	750MG	N20357 004
		NOV 05, 1998

METHACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
RONDOMYCIN

WALLACE LABS	EQ 140MG BASE	N60641 001
	EQ 280MG BASE	N60641 002

SYRUP; ORAL
RONDOMYCIN

WALLACE LABS	EQ 70MG BASE/5ML	N60641 003

METHADONE HYDROCHLORIDE

TABLET, DISPERSIBLE; ORAL
WESTADONE

EON	2.5MG	N17108 001
	5MG	N17108 002
	10MG	N17108 003
	40MG	N17108 004

METHAMPHETAMINE HYDROCHLORIDE

TABLET; ORAL
METHAMPEX

TEVA	10MG	N83889 001

METHAMPHETAMINE HCL

TEVA	5MG	N86359 001

METHARBITAL

TABLET; ORAL
GEMONIL

ABBOTT	100MG	N08322 001

METHDILAZINE

TABLET, CHEWABLE; ORAL
TACARYL

WESTWOOD SQUIBB	3.6MG	N11950 009

METHDILAZINE HYDROCHLORIDE

SYRUP; ORAL
METHDILAZINE HCL

ALPHARMA	4MG/5ML	N87122 001

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Food and Drug Administration, (Rm1061)

5630 Fishers Lane

Rockville, MD. 20852

Docket Markets Branch

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